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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Christian GUELLY et al.

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Serial No. 10/528,031

Attorney Docket No. 2005_0070A

Filed March 16, 2005

POLYPEPTIDES AND NUCLEIC ACIDS
ENCODING THESE AND THEIR USE FOR
THE PREVENTION, DIAGNOSIS OR
TREATMENT OF LIVER DISORDERS
AND EPITHELIAL CANCER

[Corresponding to PCT/EP2003/010564
Filed September 23, 2003]

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☒ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application
PCT/_____; and/or
- ☐ each reference previously cited in prior parent application Serial No.
_____.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, **or**

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

and thus no certification and/or fee is required.

1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

the certification of paragraph 2 below is provided, and

the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

2. It is hereby certified

a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or

b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification

after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.
4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ a full or partial English language translation submitted herewith,
 - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
 - c. ☐ the concise explanation contained in the specification of the present application at page,
 - d. ☐ the concise explanation set forth in the attached English language abstract,
 - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.

Respectfully submitted,

Christian GUELLY et al.

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July 7, 2005

INFORMATION DISCLOSURE STATEMENT

FORM PTO 1449 (modified)

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,736,866	4/1988	Leder et al.			
	AB	4,816,397	3/1989	Boss et al.			
	AC	4,816,567	3/1989	Cabilly et al.			
	AD	5,569,588	12/1996	Ashby et al.			
	AE	5,583,278	12/1996	Alt et al.			
	AF	5,625,122	4/1997	Mak			
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	AH	5,744,305	4/1998	Fodor et al.			
	AI	5,750,825	5/1998	Yazaki et al.			

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	AJ	196 19 373	11/1997	DE			Abstract
	AK	196 25 049	1/1998	DE			Abstract
	AL	198 16 414	10/1999	DE			Abstract
	AM	0 127 839	12/1984	EP			
	AN	0 368 684 B1 & B2	5/1990	EP			

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	AP	B. Alberts et al., eds., The Molecular Biology of the Cell, 3 rd Edition, 2002 Garland, New York, USA, pp. 98-137.
	AP	R. N. M. MacSween et al., eds., Pathology of the Liver, 4 th Edition, 2001, Churchill Livingstone, Edinburgh, pp. 598, 732.
	AQ	M. Hollander et al., eds., Nonparametric Statistical Methods, 2 nd Edition, 1973 New York, John Wiley & Sons, pp. 26-33 and 68-75.

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	BA	6,183,956	2/2001	Sivaraja et al.			
	BB						

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO	
	BC	88/01649	3/1988	WO				
	BD	93/06213	4/1993	WO				
	BE	95/11910	5/1995	WO				
	BF	97/29116	8/1997	WO				
	BG	98/24884	6/1998	WO				
	BH	98/37240	8/1998	WO				

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	BK	M. Kozak, "An analysis of 5'-noncoding sequences 699 vertebrate messenger RNAs", Nucleic Acids Research, Vol. 15, No. 20, pp. 8125-8148, 1987.
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	CC	D. F. Bauer, "Constructing Confidence Sets Using Rank Statistics", Journal of the American Statistical Association, Vol. 67, No. 339, pp. 687-690, September 1972.
	CD	R. Q. H. Zheng et al., "Inhibition of gene expression by anti-sense oligodeoxynucleotides", Clin. Exp. Immunol., Vol. 100, pp. 380-382, 1995.
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	DC						

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	DD	D. Lindemann et al., "Versatile Retrovirus Vector Systems for Regulated Gene Expression <i>In Vitro</i> and <i>In Vivo</i> ", Molecular Medicine, Vol. 3, No. 7, pp. 466-476, July 1997.
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	EB						

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	ED	S. Fields et al., "The two-hybrid system: an assay for protein-protein interactions", Trends in Genetics, Vol. 10, No. 8, pp.286-292, August 1994.
	EI	J. Sambrook et al., "Molecular Cloning", A Laboratory Manual, Second Edition, Enzymes used in Molecular Cloning, pp. 5.52-5.55, 1989.
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	EK	D. Tackels-Horne et al., "Identification of Differentially Expressed Genes in Hepatocellular Carcinoma and Metastatic Liver Tumors by Oligonucleotide Expression Profiling", Cancer, Vol. 92, No. 2, pp. 395-405, July 15, 2001.

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	FC	A. Persidis, "Ribozyme Therapeutics", Nature Biotechnology, Vol. 15, pp. 921-922, September 1997.					
	FD	M. Schena et al., "Quantitative Monitoring of Gene Expression Patterns with a Complementary DNA Microarray", Science, Vol. 270, pp. 467-470, October 1995.					
	FE	L. Beigelman et al., "Synthesis and Biological Activities of a Phosphorodithioate Analog of 2',5'-oligoadenylate", Nucleic Acids Research, Vol. 23, No. 19, pp. 3989-3994, 1995.					
	FF	D. J. Lockhart et al., "Expression monitoring by hybridization to high-density oligonucleotide arrays", Nature Biotechnology, Vol. 14, pp. 1675-1680, December 1996.					
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	GB						

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	GC	Y. Shirota et al., "Identification of Differentially Expressed Genes in Hepatocellular Carcinoma with cDNA Microarrays", Hepatology, Vol. 33, No. 4, pp. 832-840, April 2001.
	GD	C. G. Wu et al., "Distinctive gene expression profiles associated with Hepatitis B virus x protein", Oncogene, Vol. 20, pp. 3674-3682, 2001.
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	GJ	J. L. Kissil et al., "Isolation of DAP3, a Novel Mediator of Interferon-γ-induced Cell Death", The Journal of Biological Chemistry, Vol. 270, No. 46, pp. 27932-27936, November 17, 1995.
	GK	S. Zimmer et al., "A Novel Human Tocopherol-associated Protein", The Journal of Biological Chemistry, Vol. 275, No. 33, pp. 25672-25680, August 18, 2000.
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	HC	C. A. Stein, "Anti-sense Oligodeoxynucleotides - Promises and Pitfalls", Leukemia, Vol. 6, No. 10, pp. 967-974, October 1992.
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	HG	T. R. Brummelkamp et al., "A System for Stable Expression of Short Interfering RNAs in Mammalian Cells", Science, Vol. 296, pp. 550-553, April 19, 2002.
	HH	D. W. Russell et al., "Nucleotide Sequence of the Yeast Alcohol Dehydrogenase II Gene", The Journal of Biological Chemistry, Vol. 258, No. 4, pp. 2674-2682, February 25, 1983.
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	IE	A. Knappik et al., "Fully Synthetic Human Combinatorial Antibody Libraries (HuCAL) Based on Modular Consensus Frameworks and CDRs Randomized with Trinucleotides", J. Mol. Biol., Vol. 296, pp. 57-86, 2000.
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	IG	P. A. Wood, Transgenic Animal Technology, A Laboratory Handbook, Chapter 5: Retrovirus-Mediated Gene Transfer, pp. 147-176, 1994.
	II	G. M. Monastersky, Transgenic Animal Technology, A Laboratory Handbook, Chapter 6: Gene Transfer Technology: Alternative Techniques and Applications, pp. 177-219, 1994.
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	IJ	P. L. M. Jansen, "Hepatology in the 21 st Century, Gene transfer, hepatocyte transplantation, DNA chips, cyberspace and... and friendly hospital", The Netherlands Journal of Medicine, Vol. 55, pp. 287-292, 1999.
	IK	A. A. Khromykh, "Replicon-based vectors of positive strand RNA viruses", Current Opinion in Molecular Therapeutics, Vol. 2, No. 5, pp. 555-569, 2000.

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	JA	6,899,830	5/2005	Boymond et al.			Corresponds to Ref AL
	JB	2003/0157505	8/2003	Miculka et al.			Corresponds to Ref AJ
	JC	2002/0028442	3/2002	Miculka et al.			Corresponds to Ref AJ

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO	
	JD							

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	JE	C. R. Graveel et al., "Expression profiling and identification of novel genes in hepatocellular carcinomas", Oncogene, No. 20, pp. 2704-2712, 2001.						
	JI	M. F. Chen et al., "Partial hepatic resection for hepatocellular carcinoma", Journal of Gastroenterology and Hepatology, Vol. 12, pp. S329-S334, 1997.						
	JI	R. N. M. MacSween et al., eds., Pathology of the Liver, 4 th Edition, 2001, Churchill Livingstone, Edinburgh, pp. 728-730.						
	JH							
	JI							
	JI							
	JK							

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.